JAN 19 2006

K 060051

510(k) SUMMARY

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
(949) 713-8327

**CONTACT PERSON:** Cheryl Blake
V.P. Regulatory Affairs and Quality Systems

**DATE OF PREPARATION:** December 20, 2005

**NAME OF DEVICE:** Specimen Retrieval System

**CLASSIFICATION NAME:** Endoscope and Accessories 21 CFR 876.1500

**TRADE NAME:** Not Determined

**SUMMARY STATEMENT:** The Applied Medical Specimen Retrieval System is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

The Specimen Retrieval System has been found non-toxic and non-irritant when tested in accordance with ISO 10993, Part I: Biological Evaluation of Medical Devices.

The Specimen Retrieval System is a disposable, single-use device and is packaged inside a Tyvek/Mylar peel pouch, which is standard packaging material for Applied's products. The packaged product is then placed in an outer product shelf pack.

The Applied Medical disposable Specimen Retrieval System will be sterilized using Cobalt 60 Gamma Radiation, AAMI/ISO Guideline for Radiation Sterilization will be utilized to provide a Sterility Assurance Level of $10^{-6}$.

The Specimen Retrieval System is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The device introduces no new safety or effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Applied Medical Resources
c/o Mr. Morten Simon Christensen
Staff Engineer and FDA Office Coordinator
Underwriters Laboratories, Inc.
455 East Trimble Road
San Jose, California 95131-1230

Re: K060051
Trade/Device Name: Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 5, 2006
Received: January 6, 2006

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

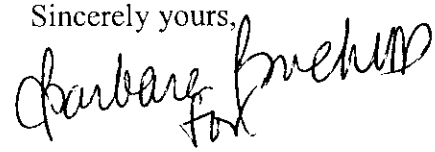
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Applied Medical Specimen Retrieval System "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Specimen Retrieval System

Indications for Use: The Applied Medical Specimen Retrieval System is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

Signature: _____
Name: *Cheryl Blake*
Title: *V.P. Regulatory Affairs and Quality Systems*
Date: *11/28/2005*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060051